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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/596,827	06/26/2006	Naoyoshi Yamada	03702/0205073-US0	1997

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EXAMINER
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MORRIS, PATRICIA L

ART UNIT	PAPER NUMBER
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1625

MAIL DATE	DELIVERY MODE
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03/14/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/596,827	<b>Applicant(s)</b> YAMADA, NAOYOSHI	
	<b>Examiner</b> Patricia L. Morris	<b>Art Unit</b> 1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 26 December 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) 10-15 and 17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 16 is/are rejected.
- 7) ☒ Claim(s) 1-3 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>2/14/07; 6/26/06</u> .  | 6) <input type="checkbox"/> Other: _____                          |

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### **DETAILED ACTION**

Claims 1-3 and 16 are under consideration in this application.

Claims 10-15 and 17 are held withdrawn from consideration as being drawn to nonelected subject matter 37 CFR 1.142(b).

### ***Election/Restrictions***

Applicant's election with traverse of Group I and the compound recited in claim 2 in the reply filed on December 26, 2007 is acknowledged. The traversal is on the ground(s) that the search and their uses would not constitute an undue burden on the examiner. This is not found persuasive because for the reasons clearly set forth in the previous Office action. Moreover, applicants have failed to advance any cogent reasons as to why the inventions are not patentably distinct. Ondeyka et al. of record shows that the compounds can be recited in separate patents and further, some of the instant compounds are well known in the art.

The restriction requirement is deemed sound and proper and will be maintained.

This application has been examined to the extent readable on the elected compound wherein R<sup>1</sup> and R<sup>2</sup> represents alkyl substituted by pyridyl as set forth in claim 1, exclusively.

Claim 16 has been examined to the extent readable on the treatment of cancer.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 16 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the

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specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is “undue”. These factors include 1) the breadth of the claims, 2) the nature of the invention, 3) the state of the prior art, 4) the level of one of ordinary skill, 5) the level of predictability in the art, 6) the amount of direction provided by the inventor, 7) the existence of working examples, and 8) the quantity of experimentation needed to make or use the invention based on the content of the disclosure. In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

No enablement can be found in the specification for the treatment of any and all cancers.

***The nature of the invention***

The nature of the invention is drawn to the method of using the instant compounds in the treatment of cancer in which inhibition of ICAM-1 is required.

***State of the Prior Art and the level of skill in the art***

It is well recognized in the art that tumor vaccines have proven largely ineffective to date. Note page 28 of Buckanovich et al. Huang et al. states that the expression of ICAM-1 on tumor cells and its role in oral cancer had not been established. Kobayashi et al. states that the precise molecular mechanism of tumor metastasis is still unclear.

***Predictability/unpredictability of the art.***

The high degree of unpredictability is well recognized in ICAM-1 inhibition. The state of the prior art is that it involves screening *in vitro* and *in vivo* to determine which compounds

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exhibit the desired pharmacological activities. There is no absolute predictability even in view of the seeming high level of skill in the art. The existence of these obstacles established that the contemporary knowledge in the art would prevent one of ordinary skill in the art from accepting any treatment regimen on its face.

***The amount of direction or guidance and the presence or absence of working examples***

The specification is silent as to whether if any compound treats cancer.

***The breadth of the claims***

The breadth of the claims are drawn to the treatment all cancers.

***The quantity of experimentation needed***

In view of high degree of unpredictability in the art, the limited working example with no results and the fact that the breadth of the claims is not commensurate with that of any objective enablement and that the nexus between inhibition of ICAM-1 and cancer has not been established, the quantity of experimentation needed would be undue when faced with the lack of direction and guidance present in the instant specification in regards to the compounds and pharmaceutical compositions.

The specification lacks direction or guidance for placing all of the alleged products in the possession of the public without inviting more than routine experimentation. Applicants are referred to In re Fouche, 169 USPQ 429 CCPA 1971, MPEP 716.02(b). Applicants are also referred to In re Wands, 858 f.2d 731,737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) which includes the incorporation of the 8 factors recited in Ex parte Foreman, 230 USPQ 546 (Bd. Of App. and Inter 1986).

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In terms of the 8 Wands factors, undue experimentation would be required to make or use the invention based on the content of the disclosure due to the breadth of the claims, the level of unpredictability in the art of the invention, and the poor amount of direction provided by applicants. Taking the above factors into consideration, it is not seen where the instant claim is enabled by the instant application.

Genentech Inc. v. Novo Nordisk A/S (CAFC) 42 USPQ2d 1001, states that “a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion” and “[p]atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable.” intended groups should not be the role of the reader. Applicants should, in return for a 20 year monopoly, be disclosing to the public that which they know as an actual demonstrated fact. The disclosure should not be merely an invitation to experiment. This is a 35 USC 112, first paragraph. If you (the public) find that it works, I claim it, is not a proper basis of patentability. In re Kirk, 153 USPQ 48, at page 53.

#### ***Allowable Subject Matter***

Claim 1 is objected to as containing nonelected subject matter. The objection may be overcome by limiting the claim to the subject matter indicated as being examinable, supra. A claim so limited would appear allowable.

Claims 2 and 3 presented in independent form or made dependent on an allowable claim would appear allowable, otherwise it is objected to as being dependent on a nonallowed claim.

#### ***Conclusion***

Claim 16 is not allowed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia L. Morris whose telephone number is (571) 272-0688.

The examiner can normally be reached on Mondays through Fridays.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Patricia L. Morris/  
Primary Examiner, Art Unit 1625

plm  
March 3, 2008